

DEC 21 2001

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

DEC 21 2001

10. **510(k) Summary of Safety and Effectiveness** (in accordance to 21 CFR 807.87(h))

Date: November 16, 2001

Device Name

Proprietary Device Name: eNTEGRA PE

Establishment Name and Registration Number of Submitter

Name: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53118

Registration Number: 2122726

Corresponding Official: D. Duersteler
Safety and Regulatory Project Engineer
GE Medical Systems EX-493
P.O. Box 414
Milwaukee, WI 53201
FAX 262-317-9190, Phone 262-317-9463

Device Classification

Classification Code: 90 LLZ

Panel Identification: Radiology

Classification Name: Picture Archiving and Communication
System (per 21CFR 892.2050)

Common Name: Nuclear Medicine Imaging Workstation

Classification Class: Class II Product

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

eNTEGRA Processing and Review Workstation (K000395)

Device Description and Intended Use of Device

The eNTEGRA PE Diagnostic Imaging Personal Digital Assistant is a device intended to provide the same functionality as the eNTEGRA Workstation (cleared in 510(k) number K000395 as the "Einstein Processing And Review Workstation"). The eNTEGRA PE is different in that this functionality is implemented on a handheld personal computer or personal digital assistant (PDA). The eNTEGRA PE will extend the

eNTEGRA P&R services to be utilized by the clinician while away from her office/desk.

The intended use of the device is to display, process, archive, and communicate data required and stored by Emission Tomography cameras and Nuclear Medicine/PET workstations.

Summary of Studies

Bench testing with representative sample images has concluded that the eNTEGRA PE system is fully functional and is operating as designed.

Conclusion

In the opinion of GE Medical Systems, the eNTEGRA PE system is substantially equivalent in terms of safety and effectiveness to the above mentioned legally marketed predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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General Electric Medical Systems
% Mr. Reiner Krumme
Division Manager Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K014058
Trade/Device Name: eNTEGRA PE Personal
Digital Assistant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving
and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 5, 2001
Received: December 10, 2001

Dear Mr. Krumme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

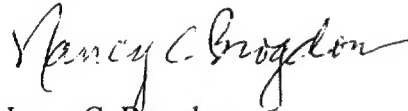
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

9. Statement Of Intended Use

K014058

Intended Use

eNTEGRA PE is designed to display, process, archive, and communicate data required and stored by Emission Tomography cameras and Nuclear Medicine/PET workstations.

It is intended that use of the device be limited to review of studies, tagging images for detailed reading, determining whether the correct images were captured, and similar uses.

The limited image size available on eNTEGRA PE has not been fully demonstrated to be suitable for diagnostic use, and it is not intended to be used for direct diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801-109)

OR Over-The-Counter Use ☐

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014058